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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,377	04/26/2001	C. Frank Bennett	RTS-0235	1027

7590 07/18/2003

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	12

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/843,377	BENNETT ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10 and 12-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,12 and 14* is/are rejected.

7)☒ Claim(s) *4-10 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This Action is in response to the communication filed on 5/8/03, as Paper No. 11. Claims 1, 2, 4-10 and 12-14 are presently pending in the application and are addressed herein.

2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Election/Restrictions

3. Applicant's election with traverse of nucleobases 1000-1092 as the targeted region in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the antisense compounds are not patentably distinct and that a serious search burden (to search all of the antisense compounds encompassed by the claims) does not exist (see p. 3-4 of the response filed 5/8/03). This is not found persuasive because the antisense compounds are patentably distinct AND searching all of the compounds encompassed by the claims would be a serious burden for the reasons of record (see the communication mailed 4/8/03, as Paper No. 10).

The requirement is still deemed proper and is therefore made FINAL.

4. Claims drawn to non-elected compounds are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Therefore, the pending claims will be examined to the extent that they read on a compound 8-50 nucleobases in length targeted to nucleobases 1000-1092, wherein the compound specifically hybridizes with the target sequence and inhibits the expression of human Interferon gamma receptor-2.

5. This application contains inventions nonelected with traverse in Paper No. 11 (see claim 1). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 and 103 that form the basis for the rejections under these sections made in this Office action:

> A person shall be entitled to a patent unless -
>
> 102(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> 103(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 12 and 14 are rejected under 35 U.S.C. 102(b) and 103(a) as being anticipated and/or obvious by Watts et al. (WO 97/15674; published May 1997).

The claims of the above invention are drawn to antisense compounds 8 to 50 nucleotides in length that specifically hybridizes within the region of nucleotides 1000-1092 of SEQ ID NO: 3 (a nucleotide sequence encoding human interferon gamma receptor-2) and inhibits the expression of a nucleotide sequence encoding human interferon gamma receptor-2 (e.g., SEQ ID

NO: 3). Claims 12 and 14 further encompasses the antisense compound in a pharmaceutically acceptable carrier or diluent.

The oligonucleotide taught by Watts (see the nucleotide sequence described as "reverse primer" on p. 14, lines 17-25) possesses 88.9% local similarity with nucleotide residues 1073-1090 of SEQ ID NO: 3 of the instant application (see attached sequence alignment), and would thus specifically hybridize with nucleotides 1073-1090 of SEQ ID NO: 3. Furthermore, Watts indicates that the "reverse primer" was used in a PCR reaction (see p. 14). Therefore the reverse primer must have been in a composition comprising water or buffer (pharmaceutically acceptable carriers/diluents). Although these references do not specifically teach the function of inhibiting applicants' instant SEQ ID NO: 3 as claimed in the present application, each of the above-listed compounds meet all the structural limitations as set forth in the instant claims. Because the sequences are substantially identical to applicant's claimed compounds, in the absence of evidence to the contrary said compounds are thus considered to possess the functional limitations of specifically hybridizing with and inhibiting the expression of applicants' instant SEQ ID NO: 3. Support for this conclusion is drawn from MPEP 2112:

> Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim **but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection**. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims. *Emphasis supplied.*

In rejecting the claims of the above under 35 U.S.C. 102 and 103, a prima facie case has been established by the examiner whereby the burden of proof in showing that the claimed

compounds are not anticipated by the compound(s) of the prior art as stated lies with the applicant, as per MPEP 2112.01:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Thus, in the absence of evidence to the contrary, the antisense compounds of claims 1, 2, 12 and 14 of the instant application are considered anticipated and/or obvious as outlined above.

Claims 1 and 12 are rejected under 35 U.S.C. 102(b) and 103(a) as being anticipated and/or obvious by Fernandez et al. (WO 99/51766; published 10/14/99).

The claims of the above invention are drawn to compounds 8 to 50 nucleotides in length that specifically hybridizes with nucleotides within the region of nucleotides 1000-1092 of SEQ ID NO: 3 (a nucleotide sequence encoding human interferon gamma receptor-2) and inhibits the expression of a nucleotide sequence encoding human interferon gamma receptor-2 (e.g., SEQ ID NO: 3).

The oligonucleotide taught by Fernandez (See the nucleotide sequence of SEQ ID NO: 5, p. 86, lines 13-20) possesses 100% local similarity with nucleotide residues 1046-1060 of SEQ ID NO: 3 of the instant application (see attached sequence alignment), and would thus specifically hybridize with nucleotides 1046-1060 of SEQ ID NO: 3. Furthermore, Fernandez indicates that the oligonucleotide is in a mixture comprising buffer and water (see p. 86), both of which are pharmaceutically acceptable carriers/diluents. Although these references do not

specifically teach the function of inhibiting applicants' instant SEQ ID NO: 3 as claimed in the present application, each of the above-listed compounds meet all the structural limitations as set forth in the instant claims. Because the sequences are substantially identical to applicant's claimed compounds, in the absence of evidence to the contrary said compounds are thus considered to possess the functional limitations of specifically hybridizing with and inhibiting the expression of applicants' instant SEQ ID NO: 3. Support for this conclusion is drawn from MPEP 2112:

> Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim **but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection**. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims. *Emphasis supplied.*

In rejecting the claims of the above under 35 U.S.C. 102 and 103, a prima facie case has been established by the examiner whereby the burden of proof in showing that the claimed compounds are not anticipated by the compound(s) of the prior art as stated lies with the applicant, as per MPEP 2112.01:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Thus, in the absence of evidence to the contrary, the compound of claim 1 of the instant application is considered anticipated and/or obvious as outlined above.

Claim Objections

6. Claims 4-10 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The instant claims are drawn to the oligonucleotides of claims 1-2 wherein the oligonucleotide comprises at least one modified internucleoside linkage, or at least one modified sugar moiety, or at least one modified nucleobase, or wherein the oligonucleotide is chimeric. Although oligonucleotides comprising modified internucleoside linkages, sugar moieties, nucleobases, etc. were well known in the art, there one of ordinary skill in the art would not have proper motivation to modify the oligonucleotides cited in the above rejections because there would have been no apparent cost effective benefit for making such modifications to the oligonucleotides.

8. Claims 1, 2, 12 and 14 are objected to because of the following informalities: claim 1 encompasses non-elected inventions. Claims 2, 12 and 14 are dependent claims and are objected to for the same reason. Appropriate correction is required.

Response to Arguments

9. Applicant's arguments, see pages 7-11 of the communication filed 2/3/03, with respect to the rejection of claims under 35 USC 112 and 35 USC 102 and 103 have been fully considered and are persuasive. Therefore, the rejection of claims set forth in the Office Action dated

10/3/02 has been withdrawn. However, new rejections have been set forth based on the newly amended claims.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. This application contains inventions nonelected with traverse in Paper No. 11 (see claim 1). A complete reply to the final rejection must include cancellation of nonelected invention or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DAVE T. NGUYEN
PRIMARY EXAMINER

J. Eric Angell
July 10, 2003